Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

- 1. (Currently amended) A process for the preparation of a dispersion of nano-crystalline particles in an aqueous medium, the process comprising the steps:
- (a) combining a first solution and an aqueous phase under rapid mixing to form a dispersion of amorphous particles, wherein:
 - (i) the first solution comprises a substantially water-insoluble substance in a water-miscible organic solvent, and
 - (ii) the aqueous phase comprises water and optionally a stabilizer.
- (b) sonicating the dispersion of amorphous particles to form nanocrystalline particles having a mean particle size of from 10 to 200 [280] nm of the substantially water-insoluble substance; and
- (c) optionally removing the water-miscible organic solvent.
- 2. (Canceled)
- 3. (Previously presented) The process according to claim 1, wherein the substantially water-insoluble substance is a pharmacologically active compound.
- 4. (Previously presented) The process according to claim 1, wherein the concentration of the substantially water-insoluble substance in the aqueous medium following step (a) is 10 mM or less.
- 5. (Previously presented) The process according to claim 4, wherein the concentration of the substantially water-insoluble substance in the combined solution and aqueous phase following step (a) is from 0.5 to 3 mM.
- 6. (Previously presented) The process according to claim 1, wherein the aqueous phase contains a stabiliser.
- 7. (Previously presented) The process according to claim 6, wherein the stabiliser comprises a polymeric dispersant and an amphiphilic surfactant.

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8. (Previously presented) The process according to claim 7, wherein the amphiphilic

surfactant is an anionic, cationic, or non-ionic surfactant.

9. (Previously presented) The process according to claim 8, wherein the polymeric

dispersant is polyvinylpyrrolidone and the anionic surfactant is sodium dodecyl sulfate.

10. (Previously presented) The process according to claim 7, wherein the amphiphilic

- surfactant is at a concentration below the critical association concentration for the

amphiphilic surfactant and polymeric dispersant.

11. (Canceled)

12. (Previously presented) The process according to claim 1, wherein rapid mixing

comprises using sonication during the combination.

13. (Previously presented) The process according to claim 1, wherein the first solution and

the aqueous phase are combined in less than 30 seconds.

14. (Previously presented) The process according to claim 1, wherein the first solution is

added to the aqueous phase.

15. (Previously presented) The process according to claim 1, wherein the dispersion of

amorphous particles is sonicated for at least 10 minutes.

16. (Previously presented) The process according to claim 1, wherein the dispersion of

amorphous particles is sonicated at a temperature below 50°C.

17. (Currently amended) The process according to claim 1, further comprising isolating the

nano-crystalline particles after formation of the nanocrystalline particles or <u>after</u> removal of

the water-miscible organic solvent.

18. (Previously presented) The process according to claim 15, wherein the dispersion of

amorphous particles is sonicated for 20 to 100 minutes.

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- 19. (Previously presented) The process according to claim 1, wherein the first solution is added to the aqueous phase, wherein the aqueous phase comprises water, a polymeric dispersant, and an amphiphilic surfactant, and the concentration of the substantially water-insoluble substance in the combined first solution and aqueous phase following step (a) is 10mM or less.
- 20. (Previously presented) The process according to claim 19, wherein the first solution and aqueous phase are combined by rapid mixing using sonication during the combination.